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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,900	09/18/2003	William F. McKay	4002-3376/PC445.00	8517
30565	7590	04/22/2008		
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 04/22/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/666,900	<b>Applicant(s)</b> MCKAY ET AL.	
	<b>Examiner</b> Brian E. Pellegrino	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-19, 27 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-19, 27 and 45-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/08 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-19,27,45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the step of holding the free end. It is not clear how the step of pulling the drawstring would cause folding when one of ordinary skill in the art would understand that pulling on an object would cause it to

move towards the location that the pulling is being done. Thus, it is not clear how the tissue is not pulled out of the implantation site when it is pulled on.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17,27,45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht et al. (2002/151979). Fig. 49G illustrates an intervertebral disc implant **400** having a length and first straight configuration with a drawstring **406** attached thereto for folding the implant in the disc space. Figs. 49C,E, 50C then shows how the implant is then manipulated to a folded second configuration. Lambrecht et al. disclose the implant material can be in a woven form, paragraph 209. The examiner is interpreting the claimed elements “braided” in this way: both braided and woven are interlaced strands or filaments. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Figs. 50C,50D,51B,51C show the implant being pulled to a folded configuration. Lambrecht also discloses the drawstring is used to pull the implant to a folded configuration, paragraph 207. It is noted that Lambrecht et al. disclose (Figs. 27,28A) the implant **38** is positioned into the nucleus and then is formed into a second folded configuration with a multiplicity of folds. The examiner is interpreting the claimed limitations “folded configuration” with multiple folds in this way: to bend (as defined by Dictionary.com) or change in direction. Claims

in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054, 1055. However, Lambrecht et al. is silent as to the pulling with the drawstring results in the configuration with multiple folds. It would have been obvious to one of ordinary skill in the art that providing an implant that has a second multiple fold configuration (Fig. 27) is capable of being established in the nucleus with the method disclosed by Lambrecht of pulling (paragraphs 207, 208, 213) the drawstring attached at a multiplicity of sites (Fig. 49G) as it is inserted in the nucleus.

Regarding claim 17, Lambrecht additionally disclose natural tissue material is used for the implant, paragraphs 31, 32. With respect to claims 45, 46, Lambrecht discloses (paragraph 207) the drawstring passes through a multiplicity of sites of the implant of at least 5, see Figs. 49G, 50F. Regarding claim 47, Lambrecht fails to explicitly disclose at least ten sites of passing the drawstring through the implant. It would have been an obvious expedient to one of ordinary skill in the art to pass the drawstring through at least 10 sites on the implant since such a modification only involves routine skill in the art and provides predictable results.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht et al. (2002/151979) in view of Muhanna (6936070). Lambrecht et al. is explained above. However, Lambrecht et al. fail to disclose the natural tissue is pericardium. Muhanna discloses that natural pericardium tissue can be used to form a

spinal implant material, col. 4, lines 51-54. It would have been obvious to one of ordinary skill in the art to substitute natural tissue and use pericardium as taught by Muhanna for the natural tissue in Lambrecht et al. spinal implant because of the abundance, availability and biocompatibility.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht et al. (2002/151979) in view of Sybert et al. (2002/107570). Lambrecht et al. is explained above. However, Lambrecht et al. fail to disclose the natural tissue is SIS. Sybert et al. discloses that natural tissue (small intestine submucosa) can be used to form a prosthetic device, paragraph 31. It would have been obvious to one of ordinary skill in the art to utilize SIS as taught by Sybert et al. for the natural tissue in Lambrecht et al. spinal implant because of the abundance of SIS and its durability.

### ***Response to Arguments***

Applicant's arguments filed 2/11/08 have been fully considered but they are not persuasive. Applicant argues that Lambrecht (2002/151979) does not teach or suggest pulling a drawstring to fold an implant to a second folded configuration having a multiplicity of folds. First, it should be noted the Applicant's representative misconstrues statements of record that the new limitation would overcome the rejection of record based on anticipation to mean it overcomes the reference. This is not what the Examiner meant and never admitted the reference does not disclose the new limitation. The rejection of record was that Lambrecht **anticipated** the claims **prior** to the amendment. The new limitation was stated by the Examiner to require new

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considerations, which **includes obviousness**. It is the Examiner's position that the invention as claimed is obvious in view of the teachings disclosed by Lambrecht. Second, it appears Applicant's representative was attempting to give some special definition to "folded" when no special definition is set forth in the written description. The Examiner, as mentioned above in the rejection, is interpreting "folded" to mean something that has been bended and the multiplicity of folds is just a bunch of bends.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738